Glossary and acronyms

Key quality terms and definitions Alphabetical Order

- **A**

Accident An undesirable or unfortunate event that occurs unintentionally.

Accreditation Procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. Reference: ISO 15189:2007.

Accreditation (and certification) body An organization or agency with the authorized right and authority to inspect a facility and provide written evidence of its compliance (certification) and competence (accreditation) with a standard.

Accuracy The closeness of a measurement to its true value.

Analytical phase *See* Examination.

Audit Systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled. Reference: ISO 9000:2005.

- **B**

Benchmark A point of reference or a criterion of quality. A benchmark is intended to serve the user as a guide for measuring optimum performance or to suggest solutions to problems or deficiencies. It implies the best practice.

Bias Difference between the expectation of the test results and an accepted reference value. Reference: ISO 15198:2004.

Biohazard An infectious agent, or part thereof, that presents a real or potential risk to the well-being of humans, animals or plants. It can present a hazard directly through infection or indirectly through the disruption of the environment.

Biological safety cabinet An enclosure in which entry and exhaust air is filtered through a high efficiency particulate air (HEPA) filter to remove any particles from potential aerosols; used to contain a biological hazard, protecting the operator and the environment. Depending on the class of the safety cabinet, it may or may not protect the actual biohazard itself from contamination.

Biological safety levels Also known as physical containment levels:

- **Biological safety level 1** A laboratory that works with agents not known to cause disease in healthy adults; standard microbiological practices apply; no special safety equipment required; sinks required.
- **Biological safety level 2** A laboratory that works with agents associated with human disease; standard microbiological practices apply plus limited access, biohazard signs, sharps precautions and biosafety manual required; biological safety cabinet used for aerosol/splash-generating operations; laboratory coats, gloves, face protection required; contaminated waste is autoclaved. An appropriate ventilation system should be in place.

- **Biological safety level 3** A laboratory that works with agents that may have serious or lethal consequences and with potential for aerosol transmission; biological safety level 2 practices plus controlled access; decontamination of all waste and laboratory clothing before laundering; determination of baseline serums; biological safety cabinet used for all sample manipulations; respiratory protection used as needed; physical separation from access corridors; double-door access; negative airflow into laboratory. The ventilation system must ensure removal of particulates by filtering entry and exhaust air through HEPA filters.
- **Biological safety level 4** A laboratory that works with dangerous or exotic agents of life-threatening nature or unknown risk of transmission; biological safety level 3 practices plus clothing change before entering laboratory; shower required for exit; all materials are decontaminated on exit; positive pressure personnel suit required for entry; separated or isolated building; dedicated air supply and exhaust with HEPA filters; and decontamination systems.

Biosafety The active, assertive, evidence-based process that laboratorians use to prevent microbial contamination, infection or toxic reaction as they actively manipulate live microorganisms or their products, thus protecting themselves, other laboratory staff, the public and the environment.

• C

Calibrators Solutions with specified defined concentrations that are used to set or calibrate an instrument, kit or system before testing is begun. Calibrators are often provided by the manufacturer of an instrument.

Certification Procedure by which a third party gives written assurance that a product, process or service conforms to specific requirements. Reference: ISO/IEC 17000:2004.

Certification (and accreditation) body An organization or agency with the authorized right and authority to inspect a facility and provide written evidence of its compliance (certification) and competence (accreditation) with a standard.

Checklist A list used to ensure all important steps or actions in an operation have been taken. Checklists contain items important or relevant to an issue or situation.

Coefficient of variation (CV) The standard deviation (SD) expressed as a percentage of the mean.

Competence Demonstrated ability to apply knowledge and skills. Reference: ISO 19011:2002.

Compliance An affirmative indication or judgement that the supplier of a product or service has met the requirements of the relevant specifications, contract or regulation; also the state of meeting the requirements. Meets both the text and the spirit of a requirement.

Confidentiality Pertains to the disclosure of personal information in a relationship of trust, with the expectation that it will not be divulged to others in ways that are inconsistent with the original disclosure.

Consensus General agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves

seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments. Reference: ISO/IEC Guide2:2004.

Continual/continuous improvement The cornerstone of quality management systems; allows the laboratory to gain insights from setting objectives, monitoring through audit and management review, addressing complaints and nonconformities, and performing client satisfaction surveys. A recurring activity to increase the ability to fulfill requirements. Includes the steps Plan, Do, Check, Act.

Continuous quality improvement A philosophy and attitude for analyzing capabilities and processes and improving them repeatedly to achieve the objective of customer satisfaction.

Control chart A chart with upper and lower control limits on which values of some statistical measure for a series of samples or subgroups are plotted. The chart frequently shows a central line to help detect a trend of plotted values toward either control limit.

Control material Substance, material or article used to verify the performance characteristics of an in vitro diagnostic medical device. Reference: ISO 15198:2004.

Controlled documentation A system for maintaining and ensuring the proper use of time-sensitive or version-sensitive documents.

Correction Action to eliminate a detected nonconformity.

Customer Organization or person that receives a product or service from a supplier organization.

Customer satisfaction Customer's perception of the degree to which the customer's requirements have been fulfilled. It can vary from high satisfaction to low satisfaction. If customers believe that you have met their requirements, they experience high satisfaction. If they believe that you have not met their requirements, they experience low satisfaction.

• D

Deming cycle for continuous improvement A visualization of the continuous quality improvement process usually consisting of four points— Plan, Do, Check, Act—linked by quarter circles. The cycle was first developed by Dr Walter A Shewhart, but was popularized in Japan in the 1950s by Dr W Edwards Deming.

Deming's 14 principles The foundation of Deming's philosophy. The points are a blend of leadership, management theory and statistical concepts that highlight the responsibilities of management while enhancing the capacities of employees.

Document Information and its supporting medium; digital or physical. The International Organization for Standardization (ISO) identifies five types of documents: specifications, quality manuals, quality plans, records and procedure documents. *See* Normative document and Standard document.

Documentation Written material defining the process to be followed.

• E

Error A deviation from truth, accuracy or correctness; a mistake; a failure of a planned action to be completed as intended, or the use of a wrong plan to achieve an aim.

Event An occurrence of some importance and frequently having an antecedent cause.

Examination 1. Activities and steps related to performing laboratory examinations. 2. Set of operations having the object of determining the value or characteristics of a property. In some disciplines (e.g. microbiology) an examination is the total activity of a number of tests, observations or measurements. Reference: ISO 15189:2007. 3. One phase of the three-phase framework for the total testing process to describe issues related to the quality of laboratory testing. Also referred to as an analytical phase. *See* Pre-examination and Post-examination.

External quality assessment (EQA) A system for objectively checking the laboratory's performance using an external agency or facility.

• F

False negative In the case of a clinical microbiology test, a negative test result for a person who is actually infected.

False positive In the case of a clinical microbiology test, a positive test result for a person who is actually not infected.

Flowchart A graphical representation of the flow of a process. A useful way to examine how various steps in a process relate to each other, to define the boundaries of the process, to identify customer and supplier relationships in a process, to verify or form the appropriate team, to create common understanding of the process flow, to determine the current best method of performing the process, and to identify redundancy, unnecessary complexity and inefficiency in a process.

Form Forms are the blank pages or computer screens, labels, or tags on which data, information, or results are recorded. After data, information, or results are entered onto a form, screen, label, or tag, it becomes a record.

• G

Gantt chart A very useful tool for visually representing the proposed time line: it shows tasks to be done, with times of beginning and completion.

Gap analysis Planning tool used to compare the present/current state with the future desired state. Basis for development of action plans to address high-priority gaps.

• I

Incident An individual occurrence of brief duration or secondary importance.

Incident report A document, usually confidential, describing any accident or deviation from policies or orders involving a patient, employee, visitor, or student on the premises of a health care facility.

Indicators Established measures used to determine how well an organization is meeting its customers' needs, as well as other operational and financial performance expectations.

Infrastructure System of facilities, equipment and services needed for the operation of an organization. Reference: ISO 9000:2005.

Informative statement Information within a document that is informational only; often it is in the form of a "note". Information may be explanatory or cautionary, or provide an example.

Inspection Examination of a product, process, service, or installation or their design and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements. Reference: ISO/IEC 17020:2012.

Internal audit An audit carried out by the laboratory personnel who examine the elements of a quality management system in their laboratory in order to evaluate how well these elements comply with quality system requirements.

ISO standards A set of international standards providing guidance for quality in the manufacturing and service industries; developed by the International Organization for Standardization (ISO) to help companies effectively document the quality system elements to be implemented to maintain an efficient quality system. The standards, initially published in 1947, are not specific to any particular industry, product or service; they are broadly applicable to many kinds of organizations.

ISO 9001:2008 The most important and internationally well-recognized series of standards for quality management are referred to as the ISO 9000 series or family. It includes a series of policy statements.

ISO 15189:2007 Standard for medical laboratories; a series of policy statements.

• L

Laboratory director Person(s) with responsibility for, and authority over, a laboratory. Reference: ISO 15189:2007.

Laboratory manager Person(s) who manage the activities of a laboratory headed by a laboratory director.

Laboratorian Person who works in a laboratory and is trained to perform laboratory procedures.

Lean A system of methods that emphasize identifying and eliminating all non-value-adding activities. Tools include S5—sort, set, shine, standardize, sustain—and CANDO—clearing up, arranging, neatness, discipline, ongoing improvement. An English phrase coined to summarize Japanese manufacturing techniques (specifically, the Toyota production system).

Licensure Granting of permission by a competent authority (usually a government agency) to an organization or individual to engage in a practice or activity.

• M

Management Coordinated activities to direct and control an organization. Reference: ISO 9000:2005.

Management review Evaluation of the overall performance of an organization's quality management system and identification of improvement opportunities. These reviews are carried out by the organization's top managers and are done on a regular basis.

Material safety data sheet (MSDS) Technical bulletin providing detailed hazard and precautionary information.

Metric A measurement for standard of quality for comparing different items or time periods—you can't improve what you can't measure. Decision makers examine the outcomes of various measured processes and strategies and track the results to guide the company and provide feedback.

- **N**

Nonconformity Non-fulfilment of a requirement. Reference: ISO 9000:2005.

Normative document A document that provides rules, guidelines or characteristics for activities or their results. It covers such documents as standards, technical specifications, codes of practice and regulations.

Normative statement Information within a document that is a required and essential part of the standard. Includes the word "shall".

- **O**

Occurrence An event, accident or circumstance that happened without intent, volition or plan.

Occurrence management A central part of continual improvement; the process by which errors or near errors (also called near misses) are identified and handled.

Organization Group of people and facilities with an arrangement of responsibilities, authorities and relationships. Reference: ISO 9000:2005.

Organizational chart Defines the working structure for the organization; organizes jobs along lines of authority; defines reporting structure and span of control; defines authority to make decisions and accountability for results; works together with job descriptions to define the working structure of the organization.

Organizational structure The pattern of responsibilities, authorities and relationships that control how people perform their functions and govern how they interact with one another.

- **P**

Path of workflow (clinical laboratory) Sequential processes in pre-examination, examination and post-examination clinical laboratory activities that transform a physician's order into laboratory information.

PDCA Plan, Do, Check, Act (quality improvement tool). A checklist of the four stages which you must go through to get from "problem faced" to "problem solved". *See* Deming cycle for continuous improvement.

Policy An overarching plan (direction) for achieving an organization's goals.

Post-examination (also post-analytical phase) Processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of the results, and storage of samples after the examinations. One phase of the three-phase framework for the total testing process to describe issues related to the quality of laboratory testing.

Precision Closeness of agreement between quantity values obtained by replicate measurements of a quantity, under specified conditions. *See* Quantitative examination.

Pre-examination (also pre-analytical phase) Steps, in chronological order from the clinician's request, including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the examination phase begins. One phase of the three-phase framework for the total testing process to describe issues related to the quality of laboratory testing.

Preventive action Plan steps that are taken to remove the causes of potential nonconformities or to make quality improvements. Preventive actions address potential problems, ones that have not yet occurred. In general, the preventive action process can be thought of as a risk analysis process.

Problem solving The act of defining a problem; determining the cause of the problem; identifying, prioritizing and selecting alternatives for a solution; and implementing a solution.

Process The use of resources to transform inputs into outputs. In every case, inputs are turned into outputs because some kind of work, activity, or function is carried out.

Process control Concerns monitoring all operations of the laboratory.

Process improvement Process management focused on reducing variation and improving process effectiveness and efficiency. Reference: ISO 3534-2:2006.

Product Result of a process; may be services, software, hardware or processed materials, or a combination thereof.

Proficiency testing 1. ISO Guide: 43 (EA-2/03): Proficiency testing schemes are interlaboratory comparisons that are organized regularly to assess the performance of analytical laboratories and the competence of the analytical personnel. 2. CLSI definition: "A programme in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification; whereby each laboratory's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratories and others". *See* External quality assessment.

Project Unique process, consisting of a set of coordinated and controlled activities with start and finish dates, undertaken to achieve an objective conforming to specific requirements, including the constraints of time, cost and resources. Reference: ISO 9000:2005.

• Q

Qualitative examination Measurement of the presence or absence of a substance, or evaluation of cellular characteristics such as morphology. The results are not expressed in numerical terms, but in qualitative terms such as "positive" or "negative"; "reactive" or "nonreactive"; "normal" or "abnormal"; and "growth" or "no growth".

Quality Degree to which a set of inherent characteristics fulfils requirements. Reference: ISO 9000:2005.

Quality assurance A planned and systematic set of quality activities focused on providing confidence that quality requirements will be fulfilled.

Quality audit (also quality assessment or conformity assessment) A systematic and independent examination and evaluation to determine whether quality activities and results comply with planned arrangements, and whether these arrangements are implemented effectively and are suitable to achieve objectives.

Quality control A set of activities or techniques whose purpose is to ensure that all quality requirements are being met. Simply put, it is examining "control" materials of known substances along with patient samples to monitor the accuracy and precision of the complete examination process.

Quality improvement Part of quality management focused on increasing the ability to fulfil quality requirements. Reference: ISO 9000:2005.

Quality indicator Established measure used to determine how well an organization meets needs and operational and performance expectations.

Quality management Coordinated activities that managers carry out in an effort to implement their quality policy. These activities include quality planning, quality control, quality assurance and quality improvement. *See* Quality system essentials.

Quality management standards (such as ISO 9001:2008 and ISO 15189:2007) A series of policy statements. Required statements include the term "shall". Full compliance with the standard requires that all "shall" statements are implemented. Were the laboratory to be inspected to ensure compliance with the standard, the auditor or inspector would expect to see evidence that each required policy was being met. "Shall" statements are often supplemented by notes or comments that often contain examples or statements using the term "should". These statements are intended to give guidance on what would be considered as reasonable activities, content or structure to demonstrate that the "shall" statement is being followed. The organization is not required to meet all the comments, suggestions or recommendations included within these notes or commentary.

Quality management system Coordinated activities to direct and control an organization with regard to quality.

Quality manual Document specifying the quality management system of an organization. Reference: ISO 9000:2005.

Quality plan Document specifying which procedures and associated resources shall be applied, by whom, and when, to a specific project, product, process or contract. Reference: ISO 9000:2005.

Quality policy Overall intentions and direction of an organization related to quality as formally expressed by top management. Reference: ISO 9000:2005.

Quality record Objective evidence which shows how well a quality requirement is being met or how well a quality process is performing. It always documents what has happened in the past.

Quality system The defined organizational structure, responsibilities, processes, procedures and resources for implementing and coordinating the quality assurance and quality control activities.

Quality system audit A documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the quality system are suitable and

have been developed, documented and effectively implemented in accordance with specified requirements.

Quality system essentials The necessary infrastructure or foundational building blocks in any organization that need to be in place and functioning effectively in order to support the organization's work operations so that they proceed smoothly. *See* Quality management. CLSI developed the quality management framework and organized the topics as the "12 Quality System Essentials" based on both ISO 15189 and CLSI GP26-A3 documents.

Quality system review A formal evaluation by management of the status and adequacy of the quality system in relation to quality policy and/or new objectives resulting from changing circumstances.

Quality tools The diagrams, charts, techniques and methods that, step by step, accomplish the work of quality improvement.

Quantification A process for calculating how much is required of any particular item for a given period of time.

Quantitative examination Measures the quantity of an analyte present in the sample. The measurement produces a numeric value as an end-point, expressed in a particular unit of measurement.

- **R**

Record Document stating results achieved or providing evidence of activities performed. Reference: ISO 9000:2005. Information captured on worksheets, forms and charts.

Referral laboratory External laboratory to which a sample is submitted for a supplementary or confirmatory examination procedure (Reference: ISO 15189:2007), or for testing not performed in the originating laboratory.

Regulation Any standard that is mandated by a governmental agency or authoritative body.

Requirement A need, expectation or obligation. It can be stated or implied by an organization, its customers or other interested parties. There are many types of requirements; some of these include quality requirements, customer requirements, management requirements and product requirements.

Risk The combination of severity of harm and probability of occurrence of that harm.

Risk analysis The systematic use of available information to identify hazards and estimate the risk.

Risk assessment Identifying potential failure modes, determining severity of consequences, identifying existing controls, determining probabilities of occurrence and detection, and evaluating risks to identify essential control points.

Risk management The identification, analysis and economic control of those risks which can threaten the assets or earnings of an enterprise.

Root cause A factor that caused a nonconformity and should be permanently eliminated through process improvement.

Root cause analysis A tool designed to help identify not only what and how an event occurred, but also why it happened.

• S

Safety Those processes implemented to protect laboratory workers, visitors, the public and environment.

Sample (also specimen) One or more parts taken from a system and intended to provide information on the system, often to serve as a basis for decision on the system or its production. Reference: ISO 15189:2007.

Semiquantitative examination Test whose results are expressed as an estimate of how much of the measured substance is present.

SI units Modernized metric system, called SI from the French name, *le Système International d'Unités*.

Six Sigma A quality process that measures defects in parts per million; stands for six standard deviations (sigma is the Greek letter "s" used to represent standard deviation in statistics) from the mean. Six Sigma methodology provides the techniques and tools to improve the capability and reduce the defects in any process by constantly reviewing and retuning the process.

Specimen *See* Sample.

Standard document A document established by consensus and approved by a recognized body that provides, for common and repeated use, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

Statistical tools Methods and techniques used to generate, analyze, interpret and present data.

Supplier Organization or person that provides a product or service.

Survey The act of examining a process or of questioning a selected sample of individuals to obtain data about a process, product or service.

• T

Task A specific, definable activity to perform an assigned piece of work, often finished within a certain time.

Team A group of individuals organized to work together to accomplish a specific objective.

Test Determination of one or more characteristics according to a procedure. Reference: ISO 9000:2005.

Traceability Ability to trace the history, application or location of that which is under consideration.

Turnaround time Length of time that a sample's final result may be issued to the ordering physician.

• U

Universal precautions An approach to infection control in which all human blood and certain human body fluids are treated as if known to be infectious.

- **V**

Validation Confirmation, through provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. Reference: ISO 15198:2004.

Verification Confirmation, through provision of objective evidence, that specified requirements have been fulfilled. Reference: ISO 15198:2004.

Verification of conformity Confirmation, by examination of evidence, that a product, process or service fulfils specified requirements.

Vision An overarching statement of the way an organization wants to be; an ideal state of being at a future point.

- **W**

Waste Any activity that consumes resources and produces no added value to the product or service a customer receives.

Work environment All the factors that influence work; these include social, cultural, psychological, physical and environmental conditions. The term work environment includes lighting, temperature, and noise factors, as well as the whole range of ergonomic influences. It also includes things like supervisory practices, as well as reward and recognition programmes. All of these things influence how work is performed.

Key quality management system acronyms Alphabetical List

- **A**

AFB acid-fast bacilli

ANSI American National Standards Institute

ASQ American Society for Quality

- **C**

CDC Centers for Disease Control and Prevention (United States of America)

CEN Comité Européen de Normalisation (European Committee for Standardization)

CLIA Clinical Laboratory Improvement Amendments (United States, 1988)

CLSI Clinical and Laboratory Standards Institute (Wayne, Pennsylvania, United States of America), uses a consensus process to develop standards

CLSI GP26-A3 *Application of a quality management system model for laboratory services* (quality document)

CLSI HS1 *A quality management system model for health care* (quality document)

- **D**

DNA deoxyribonucleic acid

- **E**

ELISA enzyme-linked immunosorbent assay

EQA external quality assessment

- **H**

HIV human immunodeficiency virus

- **I**

IATA International Air Transport Association

IEC International Electrotechnical Commission. IEC is the world's leading organization that prepares and publishes International Standards for all electrical, electronic and related technologies

ISO International Organization for Standardization

- **L**

LIMS laboratory information management system

- **M**

MSDS material safety data sheet

- **N**

NCCLS National Committee for Clinical Laboratory Standards (former name of Clinical and Laboratory Standards Institute)

- **P**

PDCA Plan, Do, Check, Act (quality improvement tool)

PT proficiency testing

- **Q**

QC quality control

- **S**

SD standard deviation

- **W**

WHO World Health Organization